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Serial No.: 10/626,261

Confirmation No.: 9585

Filed: 24 July 2003

For: HARDENABLE THERMALLY RESPONSIVE COMPOSITIONS

Remarks

The Office Action mailed 17 November 2006 has been received and reviewed. Claims 1-22, 36-39, 44, 47, and 57-59 have been canceled herein. Applicants reserve the right to prosecute the subject matter of canceled claims 1-22, 36-39, 47, and 57-59, which are drawn to non-elected groups, in Divisional and/or Continuation applications. The pending claims are claims 23, 26-29, 32-35, 40-43, 45-46, and 48-56, all of which are currently under consideration.

Reconsideration and withdrawal of the rejections are respectfully requested.

Rejection under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claim 44 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Claim 44 having been canceled herein, the rejection has been rendered moot.

Reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph, are respectfully requested.

Rejection under 35 U.S.C. §102

The Examiner maintained the rejection of claims 23, 26-29, 34-35, 40, 44-46, 48-49, and 53-56 under 35 U.S.C. §102(b) as being anticipated by Joshi et al. (U.S. Patent No. 5,252,318). Claim 44 having been canceled, this rejection is respectfully traversed as applied to claims 23, 26-29, 34-35, 40, 45-46, 48-49, and 53-56.

Independent claims 23 and 29 each recite, among other things, a thermally responsive composition including *a polymerizable component*. Applicants respectfully submit that Joshi et al. fails to disclose a thermally responsive composition including *a polymerizable component*, as discussed in the remarks on pages 15-16 of the Amendment and Response submitted 21 August 2006, which are incorporated by reference herein.

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Nonetheless, the Examiner asserted that "the crosslinking agents as disclosed by the reference (col. 3, lines 51-66) would be in a thermally responsive composition" (page 4, lines 13-14 of the Office Action mailed 17 November 2006). Again, Applicants earnestly disagree with the Examiner's conclusory allegation.

Joshi et al. at column 3, lines 51-66 recites the following:

Exemplary pH-triggered gelling polymers that produce thickening at increased pH are preferably acidic polymers such as those containing carboxyl groups. Those skilled in the art will appreciate that *small amounts of crosslinking agents such as divinyl benzene, divinyl glycol and polyalkenyl polyethers will facilitate the formation of three dimensional polymer network structures in the resultant cross-linked polyacrylates.* Carboxy vinyl linear or branched or cross-linked polymers of the monomers, such as methacrylic acid, ethacrylic acid, β -methylacrylic acid, cis- α -methylcrotonic acid, trans- α -methylcrotonic acid, α -butylcrotonic acid, α -phenylacrylic acid, α -benzylacrylic acid, α -cyclohexylacrylic acid, and the like are examples of such acidic pH-sensitive gelling polymers. (Column 3, lines 51-63; emphasis added).

Applicants respectfully submit that a careful reading of the passage as a whole would clearly convey to one of skill in the art, that Joshi et al. teach adding *crosslinking agents to monomers* used to prepare a *crosslinked polymer*, and that the combination of a *crosslinking agent* and *unpolymerized monomers* does not provide a thermally responsive composition. Further, upon polymerization of the crosslinking agent and monomers, crosslinking agent is clearly consumed in the formation of the *crosslinked polymer*. Finally, there is no disclosure in Joshi et al. that any crosslinked polymer includes unreacted crosslinking agent.

For at least this reason, Applicants respectfully submit that Joshi et al. fail to anticipate claims 23, 26-29, 34-35, 40, 45-46, 48-59, and 53-56. Reconsideration and withdrawal of the rejection under 35 U.S.C. §102 are respectfully requested.

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Rejections under 35 U.S.C. §103

The Examiner rejected claims 23, 26-29, 32-35, 40-46, 48-51, and 53-56 under 35 U.S.C. §103(a) as being unpatentable over Bromberg et al. (U.S. Patent No. 5,939,485). Claim 44 having been canceled, this rejection is respectfully traversed as applied to claims 23, 26-29, 32-35, 40-43, 45-46, 48-51, and 53-56.

"Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so >. *In re Kahn*, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006) (discussing rationale underlying the motivation-suggestion-teaching requirement as a guard against using hindsight in an obviousness analysis). The teaching, suggestion, or motivation must be found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art." M.P.E.P. §2143.01.

Independent claims 23 and 29 each recite, among other things, applying a thermally responsive composition to hard tissue of an oral surface. As acknowledged by the Examiner, Bromberg et al. "does not disclose [that] the compositions are applied to the hard tissue of the teeth" (page 5, lines 19-20 of the Office Action mailed 17 November 2006). Further, Applicants respectfully submit that one of skill in the art would have no motivation to modify the disclosure of Bromberg et al. to arrive at the presently claimed invention.

For example, Bromberg et al. recite the following:

Exemplary drugs or therapeutics delivery systems which may be administered using the aqueous responsive polymer network compositions of the invention include, but are in no way limited to, mucosal therapies, such as esophageal, otic, rectal, buccal oral, vaginal, and urological applications; topical therapies, such as wound care, skin care and teat dips; and intravenous/subcutaneous therapies, such as intramuscular, intrabone (e.g., joints), spinal and subcutaneous therapies, tissue supplementation, adhesion prevention and parenteral drug delivery. It will be appreciated that

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the ionic nature of the "structural component" component of the responsive polymer network provides *an adhesive interaction with mucosal tissue*. (Column 11, lines 21-33; emphasis added).

Bromberg et al. teach that aqueous responsive polymer network compositions can be used for pharmaceutical or cosmetic applications (e.g., column 1, line 21). Clearly, the passage recited above indicates that such pharmaceutical or cosmetic applications include delivery of drugs or therapeutics to soft tissue (e.g., "an adhesive interaction with mucosal tissue"). Applicants respectfully submit that Bromberg et al. provide no clear teaching or suggestion that aqueous responsive polymer network compositions be used for delivery of drugs or therapeutics to hard tissue, much less hard tissue of an oral surface, as recited in independent claims 23 and 29. For at least this reason, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of unpatentability for claims 23-25, 26-29, 32-35, 40-43, 45-46, 48-51, and 53-56 being obvious over Bromberg et al.

The Examiner rejected claim 52 under 35 U.S.C. §103(a) as being unpatentable over Murray (U.S. Patent No. 4,659,572). This rejection is respectfully traversed.

Claim 52 ultimately depends from independent claim 29. The deficiencies of Bromberg et al. as applied to claim 29 have been discussed herein above. Applicants respectfully submit that Murray, which "relates to surgical dressings and in particular to the covering of a wound, lesion or the like with an adherent film to effect protection therefor during the healing process" (column 1, lines 15-18), fails to provide that which is missing from Bromberg et al. For at least this reason, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of unpatentability for claim 52 being obvious over Bromberg et al. in view of Murray.

Reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) are respectfully requested.

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Summary

It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

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January 17, 2007

Date

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 17th day of January 2007, at 5:00 p.m. (Central Time).

By: 

Name: Rachel Anglin